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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,904	09/12/2003	Thomas Dawson Thomson	PDA-1003	8336

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EXAMINER	
AUGHENBAUGH, WALTER	
ART UNIT	**PAPER NUMBER**
1772	

DATE MAILED: 07/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/661,904	THOMSON ET AL.	
	Examiner	Art Unit	
	Walter B. Aughenbaugh	1772	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-14* is/are pending in the application.

4a) Of the above claim(s) *9-14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-8, drawn to flexible tubing, classified in class 428, subclass 36.9.

   II. Claims 9-14, drawn to a process of conveying an aqueous liquid, classified in class 406, subclass 191.

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process for using the product as claimed can be practiced with another materially different product such as a single-layer tube that consists essentially of thermoplastic silicone rubber.

3. During a telephone conversation with Christopher L. Parmelee on March 22, 2005 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-8. Affirmation of this election must be made by applicant in replying to this Office action. Claims 9-14 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

4. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites the limitation "the inner laminated wall" in the second line of the claim; there is insufficient antecedent basis for this limitation in the claim. Claim 1 recites the limitation "the outer laminated wall" in the fourth line of the claim; there is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

10. Claims 1 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dogan et al. in view of Sater et al.

In regard to claim 1, Dogan et al. teach a flexible tubing (catheter, col. 1, lines 6-14 and col. 3, line 3) derived from laminated polymeric materials (col. 4, lines 19-25) where the tubing has inner and outer walls (inner layer, item 16, and middle layer, item 15, respectively) where the inner wall (inner layer, item 16) consists essentially of silicone rubber (col. 4, lines 24-25), and the outer wall (middle layer, item 15) consists essentially of polymeric rubber derived from a polymeric blend comprising olefin polymers (col. 4, lines 21-24). Catheters are for aqueous systems, such as blood.

Dogan et al. fail to explicitly teach that the silicone rubber is thermoplastic.

Sater et al., however, disclose a catheter (item 15, Fig. 1 and 2) comprising an outer tubular sheath, item 130, formed of a thermoplastic material such as a thermoplastic silicone rubber (col. 7, lines 49-54 and 8-16 and Fig. 3 and 4). Since Sater et al. teach that the thermoplastic silicone rubber is the material the outer tubular sheath of the catheter (col. 7, lines 49-54), the thermoplastic silicone rubber of Sater et al. is necessarily biocompatible, and since

Dogan et al. teach that the inner wall (inner layer, item 16) that consists essentially of silicone rubber is biocompatible (col. 4, line 66-col. 5, line 1), one of ordinary skill in the art would have recognized to have used the thermoplastic silicone rubber of Sater et al. as the silicone rubber of the inner layer, item 16, of Dogan et al. in order to ensure that the inner layer of the catheter of Dogan et al. is compatible with the body fluid, such as blood, that passes through the catheter as taught by Sater et al.

Since the tubing taught by Dogan et al. and Sater et al. has an inner wall that consists essentially of thermoplastic silicone rubber, the inner wall that consists essentially of thermoplastic silicone rubber taught by Dogan et al. and Sater et al. necessarily is substantially resistant to bacteria, as Applicant admits that silicone rubber tubing does not exhibit surface cracks or bacteria contamination as experienced with conventional rubber, and the habitats for bacterial propagation is greatly minimized at lines 20-22 of page 1 of Applicant's specification in the "Background Art" section of the specification. Furthermore, since Applicant admits that "the use of thermoplastic silicone rubber tubes is expected to minimize the bacteria contamination in conventional rubber tubing" in the sentence bridging pages 1 and 2 of Applicant's specification, Applicant admits that one of ordinary skill in the art would have recognized that a tube with a inner wall of thermoplastic silicone rubber would render the tube substantially resistant to bacteria.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the thermoplastic silicone rubber of Sater et al. as the silicone rubber of the inner layer, item 16, of Dogan et al. in order to ensure that the inner layer of the catheter of

Dogan et al. is compatible with the body fluid, such as blood, that passes through the catheter as taught by Sater et al.

In regard to claim 6, Dogan et al. teach that the polymeric rubber is derived from a blend of olefinic copolymers wherein the olefins have 2, 3 or 4 carbons (the olefins are ethylene, propylene and butylene, col. 5, lines 11-15 and 30-42 and col. 5, line 66-col. 6, line 4).

11. Claims 2, 4, 7 and 8 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dogan et al. in view of Sater et al. and in further view of Chundury.

Dogan et al. and Sater et al. teach the tubing as discussed above.

In regard to claim 2, Dogan et al. teach that the polymeric rubber of the outer wall (middle layer, item 15) comprises a mixture of a thermoplastic elastomer such as styrene block copolymers and ethylene-propylene based copolymers, which are thermoplastic elastomers and olefinic copolymers (col. 4, lines 21-23). Dogan et al. teach that the styrene block copolymers comprise at least one olefinic block, such as ethylene, propylene or butylenes (col. 5, lines 11-15 and 30-42 and col. 5, line 66-col. 6, line 4); therefore the styrene block copolymers of Dogan et al. are olefinic styrene block copolymers. Since Dogan et al. teach that the polymeric rubber of the outer wall (middle layer, item 15) comprises a mixture of a thermoplastic elastomer such as styrene block copolymers and ethylene-propylene based copolymers (col. 4, lines 21-23), a plurality of thermoplastic elastomer styrene block copolymers falls within the scope of the teachings of Dogan et al., and Dogan et al. therefore teach both an olefinic styrene block copolymer component and a thermoplastic rubber component. Dogan et al. teach that the combination of the different thermoplastic elastomers totals to 6 to 100% by weight of the polymeric rubber of the outer wall (col. 7, lines 63-66).

Dogan et al. and Sater et al. fail to explicitly teach that the polymeric rubber of the outer wall comprises a maleic anhydride olefinic copolymer and fail to teach the claimed relative amounts for each of the four positively recited components of the blend.

Chundury, however, disclose a composition for medical tubing that has one or more improved properties such as kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques (col. 2, lines 23-30). Chundury disclose that the composition comprises ethylene-vinyl acetate copolymer and an ethylene-propylene copolymer, olefinic styrene block copolymers and a maleic anhydride olefinic copolymer as a compatibilizer (col. 2, lines 33-37, col. 3, lines 35-42 and 59-62, col. 4, lines 3-10, col. 5, lines 5-22 and 48-52 and col. 8, lines 49-57). Chundury disclose that the ethylene-propylene copolymer is present in the blend in an amount of 20 to 40% by weight of the blend (col. 3, lines 59-62). Chundury disclose that the olefinic styrene block copolymer is present in the blend in an amount of 0.5 to 45% by weight of the blend (col. 18, lines 23-28) and that the maleic anhydride olefinic copolymer is present in the blend in an amount of 0.5 to 45% by weight of the blend (col. 18, lines 33-36). Therefore, one of ordinary skill in the art would have recognized to have added the maleic anhydride olefinic copolymer of Chundury to the polymeric rubber of the outer wall taught by Dogan et al. and Sater et al. as a compatibilizer of the blend taught by Dogan et al. and Sater et al. in order to compatibilize the blend taught by Dogan et al. and Sater et al. so that the catheter tubing has one or more improved properties such as kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques as taught by Chundury.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the relative amounts of the components of the blend taught by Dogan et al., Sater et al. and Chundury in order to achieve the desired kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques, depending on the particular desired end result as taught by Chundury.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the maleic anhydride olefinic copolymer of Chundury to the polymeric rubber of the outer wall taught by Dogan et al. and Sater et al. as a compatibilizer of the blend taught by Dogan et al. and Sater et al. in order to compatibilize the blend taught by Dogan et al. and Sater et al. so that the catheter tubing has one or more improved properties such as kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques as taught by Chundury.

In regard to claim 4, Dogan et al. teach that the olefinic copolymer is derived from an olefin having 2 carbons and also from an olefin having 3 carbons (ethylene-propylene based copolymers, col. 4, lines 21-23).

In regard to claim 7, Chundury teach that the maleic anhydride olefinic copolymer is derived from an olefin having 2 carbon atoms (ethylene, col. 8, lines 48-53).

In regard to claim 8, Dogan et al. teach that the olefinic styrene block copolymer is derived from an olefin having 2, 3 or 4 carbons (ethylene, propylene and butylene, col. 5, lines 11-15 and 30-42 and col. 5, line 66-col. 6, line 4).

12. Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dogan et al. in view of Sater et al. and in further view of Chundury and in further view of Speth et al.

Dogan et al. and Sater et al. teach the tubing as discussed above. Dogan et al. teach that the polymeric rubber of the outer wall (middle layer, item 15) comprises a mixture of a thermoplastic elastomer such as styrene block copolymers and ethylene-propylene based copolymers, which are thermoplastic elastomers (col. 4, lines 21-23). Dogan et al. teach that the styrene-isoprene-styrene is a suitable styrene block copolymer (col. 5, lines 11-15 and 30-42). Since Dogan et al. teach that the polymeric rubber of the outer wall (middle layer, item 15) comprises a mixture of a thermoplastic elastomer such as styrene block copolymers and ethylene-propylene based copolymers (col. 4, lines 21-23), a plurality of thermoplastic elastomer styrene block copolymers falls within the scope of the teachings of Dogan et al., and Dogan et al. therefore teach a thermoplastic rubber component. Dogan et al. teach that the combination of the different thermoplastic elastomers totals to 6 to 100% by weight of the polymeric rubber of the outer wall (col. 7, lines 63-66). Dogan et al. teach that the outer wall (middle layer, item 15) may comprise tackifying agents (col. 7, lines 18-21).

Dogan et al. and Sater et al. fail to explicitly teach that the polymeric rubber of the outer wall comprises an ethylene-octene copolymer, a maleic anhydride ethylene copolymer and a phenolic resin and fail to teach the claimed relative amounts for each of the components of the blend.

Chundury, however, disclose a composition for medical tubing that has one or more improved properties such as kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding

techniques (col. 2, lines 23-30). Chundury disclose that the composition comprises ethylene-vinyl acetate copolymer and an olefinic styrene block copolymer such as styrene-isoprene-styrene and ethylene ethyl acrylate maleic anhydride copolymer and ethylene-octene copolymers as compatibilizers (col. 2, lines 33-37, col. 3, lines 35-42 and 59-62, col. 4, lines 3-10, col. 5, lines 5-22 and 48-52 and col. 8, lines 49-57). Chundury disclose that the olefinic styrene block copolymer is present in the blend in an amount of 0.5 to 45% by weight of the blend (col. 18, lines 23-28) and that the maleic anhydride olefinic copolymer is present in the blend in an amount of 0.5 to 45% by weight of the blend (col. 18, lines 33-36). Therefore, one of ordinary skill in the art would have recognized to have added the ethylene ethyl acrylate maleic anhydride copolymer and ethylene-octene copolymer of Chundury to the polymeric rubber of the outer wall taught by Dogan et al. and Sater et al. as compatibilizers of the blend taught by Dogan et al. and Sater et al. in order to compatibilize the blend taught by Dogan et al. and Sater et al. so that the catheter tubing has one or more improved properties such as kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques as taught by Chundury.

Furthermore, Speth et al. disclose an elastomeric film material for catheters (col. 2, line 62-col. 3, line 2) that comprises a tackifier such as a phenol-aldehyde resin (col. 11, lines 39-41). Since Dogan et al. teach that the outer wall (middle layer, item 15) may comprise tackifying agents (col. 7, lines 18-21), one of ordinary skill in the art would have recognized to have used the phenol-aldehyde resin tackifier of Speth et al. as tackifier in the outer wall (middle layer, item 15) of Dogan et al. since phenol-aldehyde resin is a well known tackifier for elastomeric compositions used to form catheters as taught by Speth et al.

Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have varied the relative amounts of the components of the blend taught by Dogan et al., Sater et al. and Chundury in order to achieve the desired kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques, depending on the particular desired end result as taught by Chundury.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have added the ethylene ethyl acrylate maleic anhydride copolymer and ethylene-octene copolymer of Chundury to the polymeric rubber of the outer wall taught by Dogan et al. and Sater et al. as compatibilizers of the blend taught by Dogan et al. and Sater et al. in order to compatibilize the blend taught by Dogan et al. and Sater et al. so that the catheter tubing has one or more improved properties such as kink-resistance, coilability, contact clarity, flexibility, tear-resistance, stability under stabilization conditions, and bondability under various bonding techniques as taught by Chundury and to have used the phenol-aldehyde resin tackifier of Speth et al. as tackifier in the outer wall (middle layer, item 15) of Dogan et al. since phenol-aldehyde resin is a well known tackifier for elastomeric compositions used to form catheters as taught by Speth et al.

13. Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Dogan et al. in view of Sater et al. and in further view of Speth et al.

Dogan et al. and Sater et al. teach the tubing as discussed above. Dogan et al. teach that the outer wall (middle layer, item 15) may comprise tackifying agents (col. 7, lines 18-21). Dogan et al. and Sater et al. fail to teach that the outer wall comprises a phenol-aldehyde resin.

Speth et al., however, disclose an elastomeric film material for catheters (col. 2, line 62-col. 3, line 2) that comprises a tackifier such as a phenol-aldehyde resin (col. 11, lines 39-41). Since Dogan et al. teach that the outer wall (middle layer, item 15) may comprise tackifying agents (col. 7, lines 18-21), one of ordinary skill in the art would have recognized to have used the phenol-aldehyde resin tackifier of Speth et al. as tackifier in the outer wall (middle layer, item 15) of Dogan et al. since phenol-aldehyde resin is a well known tackifier for elastomeric compositions used to form catheters as taught by Speth et al.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have used the phenol-aldehyde resin tackifier of Speth et al. as tackifier in the outer wall (middle layer, item 15) of Dogan et al. since phenol-aldehyde resin is a well known tackifier for elastomeric compositions used to form catheters as taught by Speth et al.

Conclusion

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Walter B. Aughenbaugh whose telephone number is 571-272-1488. The examiner can normally be reached on Monday-Thursday from 9:00am to 6:00pm and on alternate Fridays from 9:00am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Harold Pyon, can be reached on 571-272-1498. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Walter B. Aughenbaugh
06/24/05 WBA

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1772

6/27/05